DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

FOOD & DRUG ADMINISTRATI(
466 FERNANDEZ JUNCOS AVE
SAN JUAN, P.R. 00901-3223

June 5, 1997

WARNING LETTER
SJN-97-17

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Larry T. Miller
Vice President and General Manager
Bristol Myers Barceloneta, Inc.
P.O. Box 657
Barceloneta, PR 00617

Dear Mr. Miller:

During an inspection of your penicillin manufacturing facility located at Barceloneta, Puerto Rico conducted from May 7 to May 15, 1997, our investigator documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) in conjunction with your firm's manufacture of tablets, capsules and powders for oral suspension causing these drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. You have no documentation of Installation Qualification/Operation Qualification in accordance with 21 CFR 211.63 for several pieces of equipment used in the manufacture of drug products. This equipment includes:

[redacted] machines BMS # [redacted]
BMS #
BMS #
BMS #
[redacted] Press BMS #
Press BMS #
Filler BMS #
BMS #

2. No preventive maintenance in accordance with 21 CFR 211.67 (a) has been performed since 2/15/95 on several pieces of equipment used in the manufacture and packaging of drug products. There is no documented evidence that this is a valid preventive maintenance schedule for the equipment in question. Equipment includes:

[redacted] Filler (Tablet counter) BMS # [redacted]
(Bottle blower) BMS # [redacted]

Forty (40) complaints concerning finding of foreign matter in bottles of Amoxicillin Trihydrate Powder for Oral Suspension have been received since October 1, 1995.

3. Between approximately 8/96 and 1/97, the checkweigher machine used in the oral powder for suspension packaging area, BMS #[redacted] was out-of-service. An additional person was assigned to the line to check weights. No instructions were generated for this procedure and results were not recorded in accordance with 21 CFR 211.100 (a) & (b).

Twenty-four (24) complaints for fill deficiencies for Amoxicillin Trihydrate Powder for Oral Suspension were received for lots filled during this period.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

Please notify the San Juan District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These include seizure and/or injunction.

Your reply should be sent to the Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00906-5719, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

Samuel Jones
District Director